

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

<p>IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</p>	<p>MDL No. 2875</p>
<p>THIS DOCUMENT RELATES TO ALL CASES</p>	<p>HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK) Redacted Version</p>

**PLAINTIFFS' *DAUBERT* MOTION AND INCORPORATED
MEMORANDUM OF LAW TO PRECLUDE OPINIONS OF DEFENSE
EXPERT TIMOTHY E. KOSTY**

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I. INTRODUCTION

Timothy E. Kosty is a pharmacist first retained by Defendants at the class certification stage, and again now at this liability phase. The Court already precluded most of Mr. Kosty’s opinions at the class certification stage because he “lack[ed] even a semi-rigorous methodology.” *See* 2/8/23 Op. (ECF 2261) at 79. The Court precluded Mr. Kosty’s economics/damages opinions on how to value VCDs because he “holds no expert qualifications in the economics[] for valuing either the market forces of drug sales or supply chain flow,” and lacked a “scientifically reliable methodology.” *Id.* at 80. The Court precluded Mr. Kosty’s opinions about the views of Plaintiffs’ expert, Dr. Panagos, on how TPPs use the Orange Book in making drug reimbursement decisions, because Mr. Kosty’s “refutation of the drug industry’s ‘perceptions’ needed more reliable support than his mere disagreement.” *Id.*

Mr. Kosty now attempts to proffer the same unqualified, unreliable, and unsupported opinions that this Court precluded earlier. He opines once again that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

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The Court should once again preclude Mr. Kosty's economics/damages opinions, and his opinions about what TPPs rely on when making reimbursement decisions. Nothing has changed since his last report and this Court's order precluding the exact same opinions Mr. Kosty tries to offer again now.

As before, his economics/damages opinions lacks any scientific methodology. He still is not an economist, has no formal economics training, and has no professional experience in economics or damages modeling. He now further concedes that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

As to his opinions on TPPs' use of the Orange Book when making reimbursement decisions, once again he solely relies on his own assumptions. He still lacks any pertinent experience, and [REDACTED]

[REDACTED].

For these reasons, expressed more fully below, Mr. Kosty's opinions identified herein should be precluded.

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II. LEGAL STANDARD

A. Rule 26 and the Contents of the Expert Report

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony and specifically the contents of an expert report. Relevant to this Motion, the Rule states the following: “The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them” Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii). A failure to submit an expert report that complies with Rule 26 is an independent basis for the exclusion of the expert’s testimony. *See, e.g., Meyers v. Nat'l R.R. Pass. Corp. (Amtrak)*, 619 F.3d 729, 734 (7th Cir. 2010) (“The consequence of non-compliance with Rule 26(a)(2)(B) is exclusion of an expert’s testimony[.]” (internal quotations and citations omitted)).

Experts are therefore only permitted to testify at trial in accordance with the contents of their reports. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *see also Lipton v. Mountain Creek Resort, Inc.*, No. CV134866KMMAH, 2019 WL 4597205, at *7 (D.N.J. Sept. 23, 2019) (“[T]he court generally will not permit an expert to testify beyond the scope of his or her report.”). “Compliance with Rule 26(a)(2) is thus a condition precedent to the use of expert testimony at trial.” *ABB Air Preheater, Inc. v. Regenerative Env’t Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996).

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B. Daubert Standard

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417-18 (3d Cir. 1999). An “expert’s opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, “the expert must have ‘good grounds’ for his or her belief.” *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, “any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *Id.* at 745. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Paoli*, 35 F.3d at 742 (discussing reliability factors under *Daubert* and Third Circuit case law).

Furthermore, “*Daubert*’s gatekeeping requirement make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”” *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152

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(1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002), *aff'd*, 68 Fed. App'x 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

(i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L.Ed.2d 508 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.*, 29 F.3d 499 (9th Cir. 1994)).

Magistrini, 180 F. Supp. 2d at 594–95.

III. ARGUMENT

A. Mr. Kosty's Economics/Damages Opinions Should Be Precluded Again

1. Mr. Kosty Tries to Offer the Same Economics/Damages Opinions Previously Precluded By This Court

At class certification, one of Mr. Kosty's assignments was to [REDACTED]

[REDACTED]
[REDACTED]¹ That is, he opined on [REDACTED]
[REDACTED].

¹ Ex. 2 (Kosty 12/19/22 Rpt.) at ¶ 24.

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Mr. Kosty claimed in his earlier report that Plaintiffs' class certification expert, Dr. Rena Conti, [REDACTED] [REDACTED]. Ex. 2 (1/12/22 Rpt.) at ¶ 162. He contended that [REDACTED] [REDACTED] [REDACTED].³ He specifically called out at pages 71-72 and 90 of his earlier class report that if [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]; *id.* ¶ 177 (arguing [REDACTED] [REDACTED]). Finally, at page 87 his previous report, Mr. Kosty opined that [REDACTED] [REDACTED]. *Id.* ¶ 169 (under sub-heading [REDACTED] [REDACTED] [REDACTED]).

This Court explicitly precluded Mr. Kosty's economics/damages opinions because he was not qualified to offer them as he "holds no expert qualifications in

² Ex. 2 (1/12/22 Rpt.) at ¶ 163.

³ *Id.* ¶¶ 169, 176, 178-180.

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the economics[] for valuing either the market forces of drug sales or supply chain flow.” 2/8/23 Op. (ECF 2261) at 80. The Court also precluded his opinions because he “lack[ed] even a semi-rigorous methodology,” offered “no relevant literature or consumer market research for support,” and “lacks scientifically reliable methodology and/or necessary expert qualifications.” *Id.* at 79-80. Accordingly, the Court ruled: “Mr. Kosty’s opinions in pages 49-99 in his Report have been precluded.” *Id.* These include the opinions noted *supra* about offsets and damages calculations that appeared at pages 71-72 and 90 his earlier report.

Mr. Kosty’s December 2022 liability report simply rehashes the same economics/damages opinions already precluded by the Court. For instance, [REDACTED]

[REDACTED] Ex. 1

(12/19/22 Rpt.) at pp.8-17. He argues here, as he contended in his previous report,

[REDACTED]
[REDACTED]. *Id.* ¶ 26 [REDACTED]
[REDACTED]

[REDACTED]) (emphasis added); *see also id.* ¶¶ 22, 24; Ex. 3 (2/23/23 Tr.) at 35:18-25, 38:25 – 36:9. He also contends once again that [REDACTED]
[REDACTED]. Ex. 1 ¶ 24; Ex. 3 (2/23/23 Tr.) at 33:4 – 34:18.

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2. Mr. Kosty Remains Unqualified To Offer Economics/Damages Opinions

As Plaintiffs explained in their motion to preclude Mr. Kosty at class certification, he is a pharmacist and consultant who has [REDACTED]

[REDACTED].⁴ His professional experience exclusively relates to [REDACTED]

[REDACTED].⁵ He does not hold any degrees [REDACTED]

[REDACTED],⁶ has not made [REDACTED]

[REDACTED],⁷ and has [REDACTED]

[REDACTED].⁸

Nothing has changed qualifications-wise since the Court's February 8th class certification order precluding Mr. Kosty's economics/damages opinions due to his lack of relevant qualifications. His complete lack of training or experience renders him unqualified to speak to economic damages calculations and modeling—including purported damages offsets. “Even under Rule 702’s forgiving standard,”

⁴ Ex. 1 at ¶¶ 3-4.

⁵ *Id.* ¶¶ 2-7.

⁶ See Ex. 4 (2/24/22 Tr.) at 39:25-40:3.

⁷ *Id.* at 40:19-22.

⁸ *Id.* at 40:23-41:1.

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Mr. Kosty is not qualified “to opine here on subjects well outside his wheelhouse[.]” *Florio v. Ryobi Techs., Inc.*, No. 17-5518, 2020 WL 5234924, at *5 (D.N.J. Sept. 20, 2020); *see, e.g., In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 240 (S.D.N.Y. 2018) (courts rightly skeptical of “litigation-driven expertise”).

3. Mr. Kosty’s Economics/Damages Opinions Remain Unreliable, Unhelpful, and Unreliably Applied

Nothing has changed methodology-wise, either, since the Court precluded Mr. Kosty’s economics/damages opinions for lack of reliability at class certification.

Last year, Mr. Kosty acknowledged that [REDACTED]

[REDACTED].⁹ He also agreed, [REDACTED]

⁹ Ex. 4 (2/24/22 Tr.) at 108:16 – 110:6.

¹⁰ *See, e.g., id.* at 120:23 – 121:8, 122:7 – 123:21.

¹¹ *Id.* at 121:10 – 122:5, 155:16 – 156:17, 157:15.

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹³

Perhaps most saliently to his current report, Mr. Kosty previously conceded that his critique that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹⁵

Mr. Kosty did not remedy any of this in his current report. He makes the same assertions now about [REDACTED]

[REDACTED]. *Compare, e.g.,* Ex. 3 (2/23/23 Tr.) at 36:22 – 39:21, *with* Ex. 4 (2/24/22 Tr.) at 163:23 – 164:17. Like last year, Mr. Kosty once again [REDACTED]

¹² *Id.* at 125:21 – 127:21.

¹³ *Id.* at 144:16 – 145:3.

¹⁴ Ex. 4 (2/24/22 Tr.) at 145:5-23, 147:19-21, 178:19 – 179:6. Offsets are also irrelevant because their potential existences does not preclude class certification. *See, e.g., In re Nexium Antitrust Litig.*, 777 F.3d 9 (1st Cir. 2015) (injury occurs at moment of purchase, “whether or not that injury is later offset”).

¹⁵ Ex. 4 (2/24/22 Tr.) at 306:4-9.

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[REDACTED].¹⁶ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁶ Ex. 3 (2/23/23 Tr.) at 53:16 – 54:20; 154:23 -155:4 (“[REDACTED]

”)).

¹⁷ *Id.* at 155:5-14; *id.* at 164:23 – 165:20 (

”)).

¹⁸ Ex. 3 (2/23/23 Tr.) at 166:3-20. (

[REDACTED]).

¹⁹ Ex. 3 (2/23/23 Tr.) at 154:2 – 155:4, 164:23 – 165:20.

²⁰ Ex. 3 (2/23/23 Tr.) at 156:14-21

[REDACTED].

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[REDACTED].²² Simply put, his speculative methodology is untested, unsupported, and unapplied.

B. Mr. Kosty's Opinions on What TPPs Rely on for Reimbursement Decisions Should be Precluded Again

As he did in his prior report, Mr. Kosty once again takes issue with the opinion of Plaintiffs' expert, Dr. Kali Panagos, concerning TPPs' reliance on the Orange Book (among other information) when making drug reimbursement decisions.²³ The Court precluded this same opinion before because it lacked a "reliable methodology" and "needed more reliable support than his mere disagreement." *See* 2/8/23 Op. (ECF 2261) at 80. The Court should preclude it again because Mr. Kosty once again lacks any reliable methodology or support besides his say-so.

²¹ *Id.* at 155:15-25 ("

").

²² *Id.* at 162:5-14 (

").

²³ *See, e.g.*, Ex. 1 at ¶¶ 195-203.

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Last year, Mr. Kosty [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].²⁵

Mr. Kosty did not correct these infirmities in his current report. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].²⁶

As to his disagreement with [REDACTED]

[REDACTED]

²⁴ Ex. 3 at 360:9 – 361:16.

²⁵ Ex. 3 at 361:5-16 (

[REDACTED].”).

²⁶ This time, Mr. Kosty tries to save his *ipse dixit* opinion by citing his own experience serving as [REDACTED]. Ex. 3 (2/23/23 Tr.) at 120:22 – 121:10. [REDACTED]

[REDACTED] *Id.* at 125:13-17.

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[REDACTED]
[REDACTED]
[REDACTED] Ex. 4 (2/24/22 Tr.) at 353:12-13 [REDACTED]

[REDACTED]); *id.* at 361:5-16. But at his latest deposition, he tried to walk away from his prior testimony, claiming [REDACTED]

[REDACTED]. Ex. 3 (2/23/23 Tr.) at 87:8 – 88:22 (“[REDACTED]

[REDACTED]’’’). No matter. Mr. Kosty lacks any method or support for his assertions, save for his say-so. Such an “opinion” is unreliable and unhelpful.

As before, it is improper for an expert to offer his own opinion about another expert’s opinion when he (i) lacks any professional experience on the matter at hand (here, drug reimbursement decisions), (ii) does not rely on any facts for his naked assertion, [REDACTED], and (iii) merely dickers with a single word choice in Dr. Panagos’ report. Such an opinion is not reliably tethered to sufficient facts, and is unhelpful and confusing.

IV. CONCLUSION

For the foregoing reasons, the Court should preclude Mr. Kosty’s economics/damages opinions, as well as his opinions on what TPPs might rely on when making drug reimbursement decisions.

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Respectfully,

ON BEHALF OF PLAINTIFFS

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 13, 2023, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch

David J. Stanoch